REMARKS

Status of the claims

Claims 1-15 are pending in the subject case. However, claims 8-13 have been withdrawn from consideration by the Examiner, leaving claims 1-7, 14 and 15 under active consideration. With this paper, claim 6 has been canceled, and claim 1 has been amended to incorporate the language of original claim 6. No claims have been newly added. Upon entry of this paper, therefore, claims 1-5, 7-15 will remain pending with claims 1-5, 7, 14, and 15 under active consideration.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim rejections under 35 USC § 102

I. Claims 1-3, 5-7 and 14 stand rejected under 35 USC 102(b) as being allegedly anticipated by Faour *et al.* (USP No. 6,004,582, "Faour").

Faour teaches an osmotic device that delivers the active agent(s) to "benefit the environment of use," including sublingual and buccal environments (Col. 4, l. 4-18 and 35-42). In other words, sublingual and buccal devices of Faour deliver the active agent for absorption into the local sublingual and buccal environments. Even in the compositions of Fauor that have two agents, each agent intended to be active in a different local environment, Fauor still does not teach a pharmaceutical composition comprising an agent that does *not* get absorbed to a substantial extent at the locus of its delivery.

In contrast, the current invention, as currently claimed, is directed toward buccal or sublingual dosage forms wherein the active agent is *not* absorbed through the oral mucosa to a substantial extent.[1] Rather, sustained release matrix of the dosage form provides gradual release

[1] Support for this amendment may be found at least in original claim 6.

of the active agent over and extended period, and that active agent, once released, is swallowed and absorbed in the gastrointestinal tract.

Hence, Faour does not teach each and every element of the claimed invention. Therefore, Applicants respectfully request withdrawal of this rejection.

II. Claims 1,2, 4-7, 14 and 15 are rejected under 35 USC 102(b) as being anticipated by Lerner *et al.* (USP No. 6,197,331, "Lerner").

Lerner discloses a controlled release patch for the oral cavity. Similar to Faour, Lerner states that his compositions are designed to deliver a pharmaceutical agent for "local" treatment of the oral cavity, throat or esophagus; to provide a composition for "topical release to sites of attachment"; and to provide a composition for oral release of a pharmaceutical, allowing for "*buccal absorption.*" *See, e.g.*, col. 6, l. 64-67 and col. 7, l. 1-4.

However, as mentioned above, the claimed invention is directed toward buccal or sublingual dosage forms wherein the active agent is *not* absorbed through the oral mucosa to a substantial extent. Rather, sustained release matrix of the dosage form provides gradual release of the active agent over and extended period, and that active agent, once released, is swallowed and absorbed in the gastrointestinal tract (*i.e.*, not the oral mucosa to a substantial extent).

Hence, Lerner does not teach each and every element of the claimed invention. Therefore, Applicants respectfully request withdrawal of this rejection.

III. Claims 1,2,5-7 and 14 are rejected under 35 USC 102(b) as being allegedly anticipated by Christenson *et al.* (USP No. 3,065,143) for the reasons of record. Applicants respectfully traverse the rejection.

The present invention is directed to pharmaceutical compositions that are *released* in the oral cavity, but *absorbed* in the gastrointestinal tract. Christenson, however, teaches the use of a "traditional" pharmaceutical tablet, one that is ingested *and* consumed via the gastrointestinal

tract. (Col. 1, l. 8-11, disclosing "medicinal agents for oral administration in the form of the tablets which provide a substantially constant rate of release of the medicament *in the gastro-intestinal tract.*")

In fact, Christenson discusses that "the gum gel barrier formed on the surface of the tablet is worn away by the motion of the tablet in the gastro-intestinal tract." Ostensibly, the compositions of Christenson would fail to even release the active agent if they is held in a buccal or sublingual location as required by the present invention. Hence, Christenson cannot be held to teach a dosage form that might be held in a buccal or sublingual location.

For at least these reasons, Applicants respectfully submit that the Section 102 rejection based on Christenson is respectfully overcome and should be withdrawn.

Applicants maintain that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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